IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF:

ANTHONY BRUCE PIKE

CASE NO.: **16-978P/US**	APPLICATION NO.: **10/561,752**
CONFIRMATION NO.: **1633**	GROUP ART UNIT: **3772**
FILED: **JANUARY 26, 2006**	EXAMINER: **KERI JESSICA NICHOLSON**

FOR: **MEDICAL PROTECTION SHEETING**

DECLARATION PURSUANT TO 37 C.F.R. §1.132

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Declaration refers to U.S. Patent Application No. 10/561,752, filed on January 26, 2006, entitled, "MEDICAL PROTECTION SHEETING."

1. I, Michael George Clark, am familiar with the subject matter of U.S. Patent Application No. 10/561,752, entitled, "MEDICAL PROTECTION SHEETING". This Declaration is submitted in support of the patentability of the claimed invention.

2. I was educated at the University of Cambridge in the UK, graduating in 1965 with First Class Honors in Natural Sciences, specializing in Chemistry, Physics, Mathematics and Crystallography, and in 1969 was awarded the degree of Ph.D., also at the University of Cambridge, for my research in the field of chemical physics. I am a Fellow of both the UK Institute of Physics and the Royal Society of Chemistry and am a Chartered Engineer. I have published over 70 papers and am cited as inventor or co-inventor in granted patents for 19 inventions, mainly in the fields of functional materials and their applications.

3. I have been employed since 2004 as an executive director of three small healthcare companies which are developing products for the treatment and healing of wounds: APA Parafricta Limited, Inotec AMD Limited, and Pres-Sure Medical Limited, and from 2002 to 2006 was an executive director of Spectronic Devices Limited. I also provide consultancy advice to leading UK Universities, venture capital investors and technology companies on the patentability and market potential of new technology arising from research. I have previously held positions as Principle Technologist at Unilever (1996-2002), Chief Scientist and Acting General Manager at GEC-Marconi Materials Technology (1994-1996), Assistant Director (Science) at GEC-Marconi Hirst Research Centre (1985-94), Individual Merit Scientist UK Ministry of Defence (1974-85), and Fellow of St John's College at the University of Cambridge (1968-1974).

4. I have thoroughly read and understood the Final Office Action dated March 18, 2010 ("the Office Action") and the references cited therein.

5. The essence of the invention disclosed in the present patent application is

a. The use of woven fabric with low fabric-to-fabric friction and negligible "stiction" (i.e. $\mu s \approx \mu d$) as medical protection sheeting, and
b. Selection, by means of testing conducted by the applicant with the assistance of the UK National Physical Laboratory, of fabric with the required properties.
c. The transformation by the Applicant of such fabric into practical, useful medical products (i.e., slide sheets, bedding, clothing and coverings for dressings) that protect against effects of friction and shear.

With regard to the selection b and the Examiner's points in paragraphs 6, 15, 16, et cetera, as evidenced in paragraphs 11 and 12, below, this selection must be made by experiment. It cannot be presumed from knowledge of the fiber. Indeed, one would expect the fabric-to-fabric friction coefficients of woven fabrics to show significant "stiction", i.e. $\mu s > \mu d$.

6. With respect to paragraph 6 of the Office Action, the Examiner rejects claims as not invented by the Applicant in view of "DuPont Airbag Fibers." The Examiner states that, "as best can be understood, the medical protection sheeting as claimed by Applicant is nothing more than a sheet of material providing the claimed properties that are found in materials made by DuPont.

a. “The DuPont Airbag Fibers” are in fact fibers, not woven articles as required by the present claims.

b. The medical protection sheeting as claimed includes structural elements which are not met by the yarn alone. The medical protection sheeting includes a woven fabric and other structural limitations making the fabric suitable as bedding, slide sheets, clothing, and coverings for dressings.

7. With respect to paragraph 11 of the Office Action, The Examiner asserts that the broadest reasonable interpretation of linen is “articles or garments made from linen or a similar cloth, such as cotton; bed sheets or tablecloths.” While this is a broad interpretation, it is not the reasonable meaning to those of skill in the art.

a. The Examiner has inappropriately paraphrased and removed emphasis from the definition in the American Heritage Dictionary which reads as follows:

lin·en (lĭn′ən) KEY

NOUN:

1.
   a. Thread made from fibers of the flax plant.
   b. Cloth woven from this thread.
2. also **linens** Articles or garments made from linen or a similar cloth, such as cotton; bed sheets and tablecloths.
3. Paper made from flax fibers or having a linenlike luster.

ADJECTIVE:

1. Made of flax or linen.
2. Resembling linen.

b. The Examiner arbitrarily chose the alternate definition for “linens” instead of the primary definition for linen which is thread from fibers of the flax plant, or cloth woven from this thread, which is the appropriate meaning in the context of the present invention.

c. The term “linen” is a term of art which is well-known and well-established in the textile industry. Those of ordinary skill in the art understand that the term “linen” refers to the primary definition which is a thread made from the fiber of a flax plant or a cloth made from the thread.

d. The points in 7b and 7c are emphasized by the "note" following the definition of "linen" found in a technical publication, "Linen." Def. Textile Terms and Definitions. 10th ed. Manchester: The Textile Institute, 1995:

linen

1. Descriptive of yarns spun entirely of flax fibres.
2. Descriptive of fabrics woven from linen yarns.
3. Descriptive of articles which, apart from adornments, are made of yarns spun from flax fibres.

Note: Despite some usage of this term in non-technical circles as a generic one, e.g., linen department, baby linen, household linen, it does not apply to individual articles that do not comply with the definition.

8. By way of background, the manufacture of a woven fabric has three or more main stages each creating a new level of structure, each of which contributes to the frictional properties of the final material:

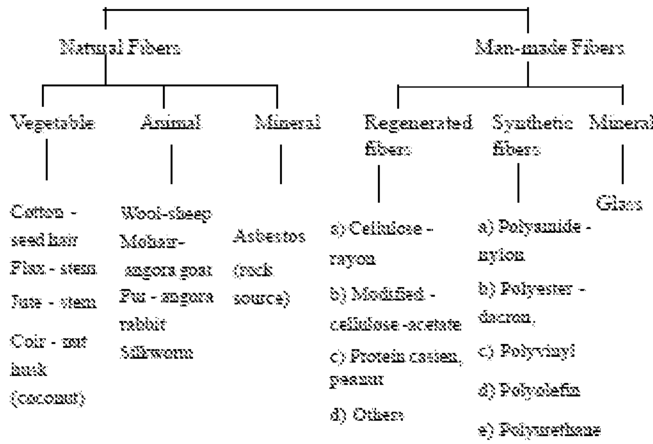
a. The first is the industrial manufacture, or the processing from natural resources, of the **fiber**. A fiber [1] is the smallest visible "unit of matter, either natural or manufactured, that forms the basic element of fabrics and other textile structures. A fiber is characterized by having a length at least 100 times its diameter or width. The term refers to units that can be spun into a yarn or made into a fabric by various methods including weaving, knitting, braiding, felting, and twisting. The essential requirements for fibers to be spun into yarn include a length of at least 5 millimetres, flexibility, cohesiveness, and sufficient strength. Other important properties include elasticity, fineness, uniformity, durability, and lustre." A fiber of an indefinite or extreme length such as found naturally in silk or manufactured by extrusion through fine jets in a spinneret are called "filaments" [1].

A broad classification of fibers [2] is shown in Table 1.

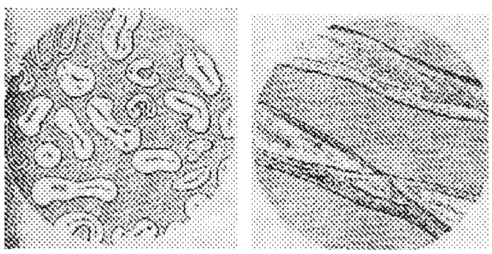
[1] Complete Textile Glossary, published by Celanese Acetate LLC, 2001

[2] http://www.textbooksonline.tn.nic.in/Books/11/Std11-HomeSci-EM.pdf

Table-1

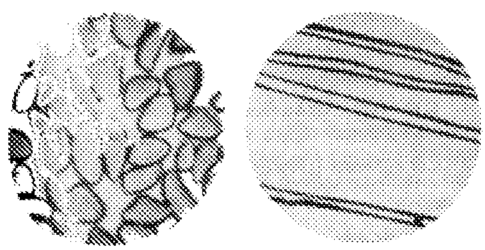


The physical properties of different textile fibers are very different, as exemplified by their different microscopic appearances[2]:



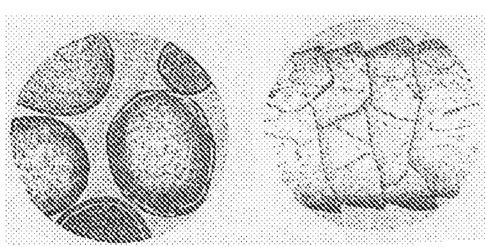
Cross Section Longitudinal

Fig. 1 - Microscopic appearance of cotton



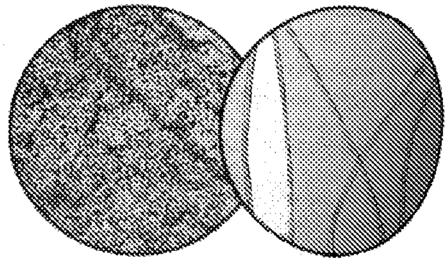
Cross Section Longitudinal

Fig.2 - Microscopic appearance of silk



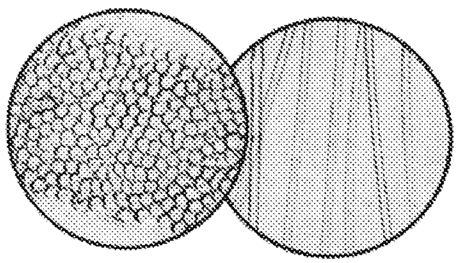
Cross Section Longitudinal

Fig.3 - Microscopic appearance of wool



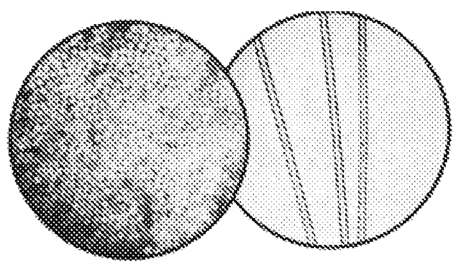
Cross Section Longitudinal

Fig.4 - Microscopic appearance of viscose rayon



Cross Section Longitudinal

Fig.5 - Microscopic appearance of polyester



Cross Section Longitudinal

Fig.6 - Microscopic appearance of nylon

b. The fibers are combined to form a **yarn**. Yarn [1] is the "generic term for a continuous strand of textile fibers, filaments, or material in a form suitable for knitting, weaving, or otherwise intertwining to form a textile fabric. Yarn occurs in the following forms: (1) a number of fibers twisted together (spun yarn); (2) a number of filaments laid together without twist (a zero-twist yarn); (3) a number of filaments laid together with a degree of twist; (4) a single filament with or without twist (a monofilament); or (5) a narrow strip of material, such as paper, plastic film, or metal foil, with or without twist, intended for use in a textile construction."

Yarns are of two types according to whether they are composed of either (1) short "staple" fibers that are derived from natural fibers that are short in length or man-made fibers or silk fibers that have been cut short or (2) long "filament" fibers such as are found naturally in silk or manufactured by extrusion through fine jets in a spinneret.

c. A **thread** may comprise either a single yarn or be composed of several yarns combined by plying or twisting.

d. Strands of thread are combined to form a textile fabric by means of **weaving**, knitting or other processes. There are many different types of weave according to how the warp and weft yarns are interlaced: plain weave; rib weave; basket weave; twill weave; satin weave; etcetera.

e. In addition, **coatings** may be applied to either the yarn prior to weaving (and not later removed) or to the woven textile. The use of coatings is not of the essence of the invention disclosed in the patent application.

9. The properties of the fibre, the type and thickness of the threads, the number of threads per unit length in each of the warp and weft directions, the pattern of the weave and its orientation, the presence or absence of any coating, all play a role in determining the friction properties of the resultant woven textile.

10. Warner [3] (cited in the Examiner's points in paragraphs 9, 11 and 27) in Tables 14.2 and 14.3 has compiled data on fiber-on-fiber friction and the friction of fibers-on-solids. As is evident from Warner's discussion pp. 248ff, these data relate to the effects of friction encountered during manufacturing processes using the fiber, such as weaving, and the avoidance of damage to either the fibre or parts of the machinery due to frictional wear.

The patent application is concerned with the friction coefficients of the woven fabric, not fiber-to-fiber or yarn-to-yarn coefficients.

Warner does not consider the friction properties of textiles woven from threads spun from the fiber. However, by way of example, the data on wool in Warner's Table 14.2 shows dramatic dependence on the orientation of the fibre which leads clearly to the conclusion that the precise weave of a textile made from wool will determine its frictional properties.

11. Das et al. [4] have reported detailed fabric-on-fabric and fabric-on-metal friction measurements of fabrics woven from 100% polyester (P), 100% viscose (V), blends of polyester with cotton (P/C = 80/20, 70/30 and 50/50) and with viscose (P/V = 40/60, 50/50, and 70/30) which showed that for fabric-on-fabric friction:

a. The coefficient of "static" friction (μs) was significantly greater than the "kinetic" or "dynamic" coefficient (μd) in all the cases measured.
b. Friction along the weft direction was slightly greater than that of the warp direction.
c. 100% polyester has lowest friction ($\mu s \approx 0.7$, $\mu d \approx 0.6$), with 100% viscose slightly higher.

[3] Steven B Warner "Fiber Science", Prentice Hall, 1995, ISBN 0-02-424541-0

[4] Apurba Das, V K Kothari and Nagaraju Vandana, "A Study on Frictional Characteristics of Woven Fabrics", AUTEX Research Journal, Vol. 5, No. 3, pp. 133-140, September 2005.

d. P/C and P/V blended fabrics show higher fabric-to-fabric friction than 100% polyester or 100% viscose – up to ≈ 50% higher for the P/C samples measured and up to ≈ 20% higher for the P/V samples.

e. P/C blended fabrics show higher frictional force by a factor of up to ≈ 1.25 times than that of P/V blended fabrics for the same parameters of the fabrics.

f. Fabric-on-metal friction was much lower (≈ one-fifth) in all cases.

The mechanisms that may contribute to these observations include:

a. Compression and/or distortion of the thread.

b. Surface characteristics of the thread.

c. Compression and/or distortion of the weave.

d. Geometry of the weave.

e. Microstructure of the weave.

Lima et al. [5], using a rotating annular upper body in place of the more conventional linear motion of a sledge, have reported significant changes in fabric-on-fabric μd of a plain weave cotton fabric in three different processing stages, raw, dyed and finished (μd = 0.396, 0.485 and 0.528, respectively).

They also measured "not finished" and "finished" samples of both the same plain-weave cotton fabric and a twill-weave cotton fabric against a standard woollen fabric "SM 25" used in the industry-standard Martindale test for abrasion resistance of fabrics [6] and against polished stainless steel.

Values of μd	SM 25	Stainless steel
Plain weave – not finished	0.408	0.147
Plain weave – finished	0.415	0.154
Twill weave – not finished	0.389	0.154
Twill weave - finished	0.430	0.173

These results again demonstrate the complexity of the relationship between fiber, thread and weave and the friction properties of a woven fabric. The friction properties

[5] M Lima, L Hes, R Vasconcelos and J Martins, "FRICTORQ, Accessing Fabric Friction with a Novel Fabric Surface Tester", AUTEX Research Journal, Vol. 5, No. 4, pp. 194-201, December 2005.

[6] http://images.wool.com/pub/TM_112_Abrasion_Resistance_of_Fabrics_Martindale_Machine_Method.pdf

of the woven fabric cannot be predicted on the basis of knowledge of the fibre and can only be established by experimental measurement.

12. It is well established that in general the coefficient of "static" friction (μs) between two surfaces is greater than the "kinetic" or "dynamic" coefficient (μd). This can be rationalised by both atomistic and microstructural theories by essentially the same argument, namely that some form of "bonding" between the materials must be "broken" before relative movement between the surfaces can commence. "Bonding" in this context includes not only the various types of chemical bond but also all other mechanisms of interaction between the two materials, including physical forces, interpenetration of the materials, geometric entanglements, etcetera.

In order to quantify the universality of this effect the declarant has collected a range of published data on measurements of μs and μd (Appendix 1). Although these data cover a wide variety of materials a regression analysis shows that on average:

$$\mu s - \mu d = 0.0487\mu d + 0.0437$$

with an R^2 value of 0.7929. The R^2 coefficient lies in the range zero to one and is a measure of how well the regression equation fits the measured values, with $R^2 = 1$ corresponding to a perfect fit. Given the nature of the data set and the errors intrinsic to the measurement of coefficients of friction, the value $R^2 = 0.7929$ indicates a good fit.

Thus the expectation for the materials disclosed in the patent application, which have $\mu d \approx 0.25$ would be that $\mu s - \mu d \approx 0.056$, contrary to the negligible values actually measured.

Note that in the limit $\mu d = 0$, μs is still greater than zero as would be predicted by the theories mentioned above.

Also explicable from the theories mentioned are exceptions to $\mu s > \mu d$ due to there being predictably no "bonding" between the two surfaces: for example it is found [e.g.4,5] that $\mu s \approx \mu d$ for woven fabrics in contact with smooth steel or aluminium plates. The nature of these metal surfaces offers no opportunity for "bonding" interactions with the woven fabric.

On the other hand, given the availability of the fabric-to-fabric "bonding" interactions discussed above it is unexpected that $\mu s \approx \mu d$ for contact between the fabrics disclosed in the patent application.

13. Except where noted otherwise, the measurements of friction coefficients cited in this declaration were made by measuring the normal and frictional forces exerted on a sledge moved across a supporting plate by methods that generally were compliant with ASTM Standard D 1894 [7] but (since D 1894 relates to films and sheeting) with normal forces and speeds of relative motion adjusted to values judged by the measurer to be more appropriate to measurements on woven textiles.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the lie so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated this 18th day of August, 2010.

M. G. Clark

Michael George Clark

[7] ASTM Standard D 1894 "Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting".

Appendix 1

* = lubricated		STATIC	SLIDING
Synovial joints (human)	Synovial joints (human)	0.01	0.003
Teflon*	Steel*	0.04	0.04
Teflon	Teflon	0.04	0.04
Teflon*	Teflon*	0.04	0.04
Steel(hard)*	Steel(hard)*	0.08	0.07
Steel(hard)*	Babbitt (ASTM No 1)*	0.08	0.11
Steel(hard)*	Babbitt (ASTM No 8)*	0.09	0.07
Ice	Ice	0.1	0.03
Waxed ski	Snow	0.1	0.05
Steel*	Steel*	0.1	0.055
Steel(hard)*	Babbitt (ASTM No 10)*	0.1	0.055
Steel*	Wood*	0.1	0.06
Steel*	Cast iron*	0.1	0.075
Steel(hard)*	Babbitt (ASTM No 8)*	0.11	0.065
Steel(hard)*	Babbitt (ASTM No 10)*	0.12	0.06
PTFE	PTFE	0.135	0.075
Waxed wood	Wet snow	0.14	0.1
Steel(hard)*	Babbitt (ASTM No 1)*	0.15	0.06
Wood*	Wood*	0.16	0.1
Steel*	CuPb alloy*	0.16	0.145
FEP	FEP	0.16	0.19
Steel(hard)*	Babbitt (ASTM No 8)*	0.17	0.14
Steel(mild)*	Cast iron*	0.183	0.133
Apple (Gala)	Plastic	0.21	0.19
Steel	Cast iron	0.215	0.205
Steel(hard)*	Babbitt (ASTM No 1)*	0.23	0.16
Cu	Stainless steel	0.23	0.21
Steel(hard)*	Babbitt (ASTM No 10)*	0.25	0.13
Apple (McLemore)	Plastic	0.25	0.21
Steel	Steel	0.255	0.2
Apple (Gala)	Masonite	0.27	0.24
Ni*	Ni*	0.28	0.12
Rubber	Concrete (wet)	0.3	0.25
Apple (Gala)	Paper	0.31	0.25
Apple (McLemore)	Paper	0.33	0.23
Linen	Parfricta (HW "along")	0.33	0.29
Glass*	Glass*	0.35	0.105
Ti alloy Ti-6Al-4V(Grade 5)	Bronze	0.36	0.27
Ti alloy Ti-6Al-4V(Grade 5)	Ti alloy Ti-6Al-4V(Grade 5)	0.36	0.3
ETFE	ETFE	0.37	0.35
Wood	Wood	0.375	0.2
Parafricta (HW "along")	Linen	0.38	0.33
Apple (McLemore)	Masonite	0.4	0.33

Ti alloy Ti-6Al-4V(Grade 5)	Al alloy 6061-T6	0.41	0.38
Steel(hard)	Babbitt (ASTM No 8)	0.42	0.35
Apple (Gala)	Rubber	0.48	0.57
Steel*	Pb*	0.5	0.3
Steel(mild)	Brass	0.51	0.44
Cu	Steel(mild)	0.53	0.36
Oak	Oak(X grain)	0.54	0.32
Steel	Wood	0.6	0.35
Wood	Wood	0.6	0.35
Al	Steel(mild)	0.61	0.47
Leather	Oak(// grain)	0.61	0.52
Oak	Oak(// grain)	0.62	0.48
Apple (McLemore)	Rubber	0.63	0.56
Linen	Linen	0.67	0.44
Cu	Glass	0.68	0.53
Steel(hard)	Babbitt (ASTM No 1)	0.7	0.33
Steel(mild)	Steel(mild)	0.74	0.57
Steel(hard)	Steel(hard)	0.78	0.42
Glass	Ni	0.78	0.56
Zinc	Cast iron	0.85	0.21
Ni	Ni	0.9	0.53
Glass	Glass	0.95	0.4
Steel	Pb	0.95	0.95
Rubber	Concrete (dry)	1	0.8
Cu	Cast iron	1.05	0.29
Cast iron	Cast iron	1.1	0.15